

In re F	Patent Application of: AOKI, et al.,))
Serial Number: 09/550,371) Filed: April 14, 2000)		Examiner: C.M. KAM Group Art Unit: 1646
	METHOD FOR TREATING PAIN BY) PERIPHERAL ADMINISTRATION) OF A NEUROTOXIN))) Irvine, California

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Applicant herewith submits a one- page form PTO 1449 for consideration by the Examiner, consistent with the provisions of 37 CFR § 1.97 and 1.98. By submitting this Information Disclosure Statement, Applicant makes no admission that any item listed thereupon is material to the patentablility of the invention claimed in the above-entitled patent application. Further, Applicant makes no assertion hereby that a search was conducted, or if conducted, that any search was thorough.

Applicant respectfully requests that the Examiner indicate consideration of the cited reference by returning a copy of the attached form PTO-1449 with the Examiner's initials or other appropriate marks.

If any fee is required please charge Deposit Account No. 01-0885 the appropriate amount and please consider this communication a petition requesting

consideration of this supplemental IDS.

Date: September 13, 2001

Allergan, Inc.

2525 Dupont Drive, T2-TH

Irvine, CA 92612 Tel: 714 246 4026 Fax: 714-246-4249 Respectfully submitted,

Stephen Donovan

Registration Number 33,433

CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. §1.10

I hereby certify that this Supplemental Information Disclosure Statement is being deposited with the United States Postal Service on **September 13, 2001** in an envelope as "Express Mail Post Office To Addressee" mailing label number EL385557033US with sufficient postage for Express Mail addressed to Assistant Commissioner for Patents, Washington, D.C., 20231.

Susan Bartholomew

Name of person mailing paper

Signature of person mailing paper

Date: September 13, 2001

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FORM PTO-1449

Sheet	1	of	1

Ŧ	IST	OF	ART	CITED	RV	APPI	ICANT

ATTY. DOCKET: 17328	SERIAL NO.: 09/550,371
APPLICANT: AOKI, ET AL.,	TITLE: METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE: April 14, 2000	GROUP:

UNITED STATES PATENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	6,113,915	9/5/00	AOKI	424	236	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (yes/n)			

OTHER ART

EXAMINER	DATE CONSIDERED

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Aoki et al.) Examiner:
U.S. Serial No.:	09/550,371) Art Unit:
Filed:	April 14, 2000)
For:	METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN))))

SUPPLEMENTARY INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Applicant provides with regard to the above-referenced patent application one copy the document listed on the attached Form PTO-1449, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56.

While this document may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that any such document is prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge Deposit Account Number 01-0885 for any fees or charges associated with the filing of this paper and any of the attached pages and to refund any overpayment to the same deposit account.

Respectfully submitted,

Registration Number 33,433

Date: November 28 2000

Allergan, Inc. 2525 Dupont Drive Irvine, CA 92612

Telephone: 714 246 4026

Fax: 714 246 4249

U.S. Serial Number: 05,550,371 Filed: April 14, 2000

Docket No: 17328 (AP)

********* ***********

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this Supplementary Information Disclosure Statement and any additional documents set forth as being enclosed herein are being deposited with the United States Postal Service on the date shown below, with sufficient postage as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, DC 20231.

Maria Zirbes
Name of Person Mailing

Signature of Person Mailing

Date: 11.28.00

U.S. Departm	ent of Cor	nmerce, Patent and	Atty Docke	Atty Docket No.		Serial No.		
	09/550,37	71						
INFO	RMATIO	N DISCLOSURE S	TATEMENT B	Y APPLICANT	Applicant(s	s) Aoki et al.		
		(Use several sheet	s if necessary)					
		-, -, -, -, -, -, -, -, -, -, -, -, -, -			Filing Date	October 4, 2000	Group	
			U.S.	Patent Documents				
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Initial		Number	Date 5/26/00	Name First	Class	Subclass	If Approp	riate
	AA	6,063,768	3/20/00	FIISt	<u> </u>			
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		Document	Date	Country	Class	Subclass	Yes	No
	AL							1
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		OTHER A	ART (Including	Author, Title, Date, Po	ertinent Pages.	Etc.)		
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Date: December 3, 2001

AOKI, et al.

Examiner: Chih-Min-Kam

Serial Number: 09/550,371

Group Art Unit: 1653

Filed: April 14, 2000

For: METHODS I

METHODS FOR TREATING PAIN

BY PERIPHERAL

ADMINISTRATION OF A

NEUROTOXIN

EL385558997US

Irvine, California

SUPPLEMENTARY INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents U.S. Patent and Trademark Office P.O. Box 2327 Arlington, VA 22202

Dear Sir:

Applicant provides with regard to the above-referenced patent application a copy of the document listed on the attached 1-page Supplementary Information Disclosure Citation (Form PTO-1449), which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56.

While this document may be material pursuant to 37 C.F.R. §1.56, the disclosure is not intended to constitute an admission that any such document is prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement. These documents were disclosed in an International Search Report in the foreign counterpart of the above-identified application, and the International Search Report was received less than three (3) months ago.

ATTORNEY DOCKET 17328(BOT)

The Commissioner is hereby authorized to charge any fees associated with this communication, or credit any overpayment, to Deposit Account No. 01-0885.

Date: December 3, 2001

Respectfully submitted,

Allergan, Inc.

2525 Dupont Drive, T2-7H

Irvine, CA 92612 Tel: 714 246 4026 Fax: 714-246-4249 Sternen Donovan

Redistration Number 33,433

CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. §1.10

I hereby certify that this Supplemental Information Disclosure Statement is being deposited with the United States Postal Service on **December 3, 2001** in an envelope as "Express Mail Post Office To Addressee" mailing label number EL385558997US with sufficient postage for Express Mail addressed to Assistant Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202.

Susan Bartholomew

Name of person mailing paper

Date: December 3, 2001

Signature of person mailing paper

SUPPLEMENTAL LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17328 (BOT)	SERIAL NO.: 09/550,371
APPLICANT: AOKI, et al.	TITLE: METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATIONOF A NEUROTOXIN
FILING DATE: APRIL 14, 2000	GROUP: 1653

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	6,113,915	9/5/00	AOKI	424		
	AB						
	AC						
	AD		•				
	AE						

FOREIGN PATENT DOCUMENTS

Γ		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
F	BA	WO 97/34624	9/25/97	PCT			(yes/no)
r	BB	WO 96/33273	10/24/96	PCT			
Г	BC	WO 95/30431	11/16/95	PCT			

OTHER ART

		(Including Author, 11tle, Date, Pertinent Pages, etc.)
	CA	Guyer, B., Mechanism of botulinum toxin in the relief of chronic pain, Current Review of Pain, 1999, 3:427-431, XP-001031379
	СВ	Carruthers, A., et al., Improvement of tension-type headache when treating wrinkles with botulinum toxin A injections, Headache, Oct. 1999:39:662-665, XP-001031356
-	CC	Diaz, J., et al., Management of post-thoracotomy pseudoangina and myofascial pain with botulinum toxin, Anesthesiology, V 91, No. 3, Sep 1999, pp. 877-879, XP-001031347
	CD	Silberstein, S., et al., Botulinum toxin type A as a migraine preventive treatment, Headache 2000:40:445-450, XP-002182692
	CE	Gobel, H., et al., Evidence-based medicine: botulinum toxin A in migraine and tension-type headache, Journal of Neurology, 2001 248 Supp 1: I/34-I/38, XP-002182693

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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application	of: DONOVAN, Stephen)	Examiner:
U.S. Serial No.:	09/550,371)	Art Unit: 1646
Filed:	April 14, 2000)	
For:	METHOD FOR TREATING PAIN BY PERIPHERAL)	
	ADMINISTRATION OF A NEUROTOXIN	<u>)</u>	Irvine. California

SUPPLEMENTARY INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Applicant provides with regard to the above-referenced patent application one copy of each of the eight documents listed on the attached Form PTO-1449, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. Please note that the Li, Schantz and Zhou articles were originally cited by applicant at the time the application was filed; however; copies of those references were not available at that time and are therefore being submitted herein.

While these documents may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that any such document is prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees associated with this communication, or credit any overpayment, to Deposit Account No. 01-0885.

Respectfully submitted,

Date: August 9, 2000

Stepher Donovan

Registration Number 33,433

Docket No. 17328 (AP)

Allergan, Inc. 2525 Dupont Drive Irvine, CA 92612 Telephone: 714 246 4026

Fax: 714 246 4249

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this Supplementary Information Disclosure Statement and any additional documents set forth as being enclosed herein are being deposited with the United States Postal Service on the date shown below, with sufficient postage as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, DC 20231.

Mary Stickle
Name of Person Mailing

Date: August 10, 2000

Signature of Person Mailing

Sheet1	of _ 1
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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FORM PTO-1449

LIST OF ART CITED BY APPLICANT

ATTY. DOCKET:	17328(AP)	SERIAL NO.: 09/550,371
APPLICANT:	A ki et al.	TITLE: METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE:	04/14/2000	GROUP: 1646

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	6,063,768	5/16/00	FIRST			
	AB			,			

FOREIGN PATENT DOCUMENTS

Г		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/n)
	BA						
	BB						

OTHER ART

(A Cheng, Guang-Shing; Botox, Dermabrasion Treated Facial Leiomyomas; Skin & Allergy News 2000;31(3):16.
(First, E. et al.; Painful Cervical Dystonia: Response to Treatment with Botulinum Toxin; Mov Disord 1998;13(Suppl2):100.
C	Guyer, Barry M.; Mechanism of Botulinum Toxin in the Relief of Chronic Pain; Curr Rev Pain 1999;3(6):427-431.
C	Li, Yan, et al.; A Single Mutation in the Recombinant Light Chain of Tetanus Toxin Abolishes Its Proteolytic Activity and Removes the Toxicity Seen after Reconstitution with Native Heavy Chain; Biochemistry 1994, 33, 7014-7020.
C	E Schantz, Edward J., et al.; Properties and Use of Botulinum Toxin and Other Microbial Neurotoxins in Medicine; Microbiological Reviews Mar. 1992, pp. 80-99, Vol. 56, No. 1.
	Tarsy, Daniel, et al.; Painful Cervical Dystonia: Clinical Features and Response to Treatment With Botulinum Toxin; Mov Disord 1999;14(6):1043-1045.
C	Zhou, Liqing, et al.; Expression and Purification of the Light Chain of Botulinum Neurotoxin A: A Single Mutation Abolishes Its Cleavage of SNAP-25 and Neurotoxicity after Reconstitution with the Heavy Chain; Biochemistry 1995, 34, 15175-15181.
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	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is	in conformance with MPEP 609; Draw line through citation if not in
conformance and not considered. Include copy of this form with next com	nmunication to applicant.

ATTORNEY DOCKET 17328(AP)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	AOKI, et al.)	Examiner:
U.S. Serial No.:	Pending)	Art Unit:
Filed:	(Herewith))	
	R TREATING PAIN BY PERIPHERAL)))	Irvine, California

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Applicant wishes to call to the attention of the Examiner the documents cited on the accompanying Form PTO-1449. No concession is made that these documents are prior art, and applicant expressly reserves the right to antedate the documents as may be appropriate. Applicant requests that each of these documents be made of record in the above-identified application.

Respectfully submitted,

Date: April 14, 2000

Allergan, Inc. 2525 Dupont Drive Irvine, CA 92612

Telephone: 714 246 4026

Fax: 714 246 4249

Registration Number 33,433

CERTIFICATE OF EXPRESS MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this Transmittal Letter and the additional documents set forth above as being enclosed herein are being deposited with the United States Postal Service on April 14, 2000, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EL079092522US, addressed to BOX PATENT APPLICATION, Assistant Commissioner for Patents, Washington, DC 20231.

STEPHEN DONOVAN

Name of person mailing paper

Signature of person mailing paper

Date: April 14, 2000

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FORM PTO-1449





ATTY. DOCKET:	17328(AP)	SERIAL NO.:
APPLICANT:	AOKI et al.	TITLE: METHOD FOR TREATING PAIN BY PERI- PHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE:	(Herewith)	GROUP:

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	5,714,468	2/3/98	BINDER			
	AB	5,766,605	6/16/98	SANDERS ET AL.			
	AC	5,989,545	11/23/99	FOSTER ET AL.			

FOREIGN PATENT DOCUMENTS

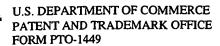
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
BA	94/15629	7/21/94	PCT			
BB	96/33273	10/24/96	PCT			
BC	98/07864	2/26/98	PCT			
BD	99/17806	4/15/99	PCT			

OTHER ART

CA	Barwood, Shane, et al.; Analgesic Effects of Botulinum Toxin A: A Randomized, Placebo-
	Controlled Clinical Trial; Developmental Medicine & Child Neurology, 2000; 42:116-121
СВ	Bigalke, H., et al.; Botulinum A Neurotoxin Inhibits Non-Cholinergic Synaptic Transmission
	in Mouse Spinal Cord Neurons in Culture; Brain Research, 360 (1985); 318-324.
CC	Bigalke, H., et al.; Tetanus Toxin and Botulinum A. Toxin Inhibit Release and Uptake of
'	Various Transmitters, as Studied with Particulate Preparations from Rat Brain and Spinal
	Cord; Naunyn-Schmiedeberg's Arch. Pharmacol (1981); 316:244-251.
CD	Cheshire, et al.; Botulinum Toxin in the Treatment of Myofascial Pain Syndrome; Pain, 1994;
	59(1):65-9.
CE	DiStefano, P. S., et al.; Receptor Mediated Retrograde Axonal Transport of Neurotrophic
	Factors is Increased After Peripheral Nerve Injury; Progress in Brain Research (1994); Vol.
	103; Chapter 4; 35-42.

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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.





ATTY. DOCKET:	17328(AP)	SERIAL NO.:
APPLICANT:	AOKI et al.	TITLE: METHOD FOR TREATING PAIN BY PERI- PHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE:	(Herewith)	GROUP:

OTHER ART (Continued)

(Including Author, Title, Date, Pertinent Pages, etc.)

	CF Dixon, W. J.; Efficient Analysis of Experimental Observations; Ann. Rev. Pharmacol.
	<u>Toxicol.</u> (1980); 20:441-462.
	Dubuisson, D., et al.; The Formalin Test: A Quantitative Study of the Analgesic Effects of Morphine, Meperidine, and Brain Stem Stimulation in Rats and Cats; Pain (1977); 4:161-174.
	Duc, C., et al.; Ultrastructural Localization of SNAP-25 Within the Rat Spinal Cord and Peripheral Nervous System; The Journal of Comparative Neurology (1995); 356:152-163.
	Fauci, A.S., et al. (Editors); <u>Harrison's Principles of Internal Medicine</u> , 14 th Edition (1998); McGraw-Hill; 2064-2065.
	Garner, C.G., et al.; Time Course of Distant Effects of Local Injections of Botulinum Toxin; Movement Disorders; Vol. 8, No. 1; 1993.
C	Habermann, E.; Inhibition by Tetanus and Botulinum A Toxin of the Release of (³ H)noradrenaline and (³ H)GABA from Rat Brain Homogenate; Experientia 44 (1988); 224-226.
C	Habermann, E.; I-Labeled Neurotoxin from Clostridium Botulinum A: Preparation, Binding to Synaptosomes and Ascent to the Spinal Cord; Naunyn Schmiedeberg's Arch. Pharmacol.; 281, 47-56 (1974).
C	M Habermann, E., et al.; Tetanus Toxin and Botulinum A and C Neurotoxins Inhibit Noradrenaline Release from Cultured Mouse Brain; Journal of Neurochemistry; Vol. 51; No. 2 (1988); 522-527.
C	Hagenah, R., et al.; Effects of Type A Botulinum Toxin on the Cholinergic Transmission at Spinal Renshaw Cells and on the Inhibitory Action at Ia Inhibitory Interneurones; Naunyn-Schmiedeberg's Arch. Pharmacol.; 299, 267-272 (1977).
С	Halpern, J.L., et al.; Neurospecific Binding, Internalization, and Retrograde Axonal Transport; Date Unknown; pp. 221-241.
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EXAMINER

DATE CONSIDERED

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FORM PTO-1449

LIST OF ART CITED BY APPLICANT

ATTY. DOCKET:	17328(AP)	SERIAL NO.:
APPLICANT:	AOKI et al.	TITLE: METHOD FOR TREATING PAIN BY PERI- PHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE:	(Herewith)	GROUP:

OTHER ART (Continued)

(Including Author, Title, Date, Pertinent Pages, etc.)

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		Spinal Nerve Ligation in the Rat; Pain, 50 (1992); 355-363.
	CS	Li et al.; Biochemistry; 33:7014-7020 (1994).
	<u> </u>	
	CT	Mochida, S., et al.; Impairment of Syntaxin by Botulinum Neurotoxin C ₁ or Antibodies
	1	Inhibits Acetylcholine Release but not Ca ²⁺ Channel Activity; Neuroscience (1995); Vol. 65;
	}	No. 3; 905-915.
	CU	Naumann, et al.; Botulinum Toxin Type A in the Treatment of Focal, Axillary and Palmar
		Hyperhidrosis and Other Hyperhidrotic Conditions; European Journal of Neurology, 1999;
		Vol. 6(suppl4):S3-S10 and S111-S115.
	CV	Nelson, P.G., et al.; Mouse Spinal Cord in Cell Culture. IV. Modulation of Inhibitory
	1	Synaptic Function; Journal of Neurophysiology; Vol. 40, No. 5; Sept. 1977; 1178-1187.
	CW	Osen-Sand, A., et al.; Inhibition of Axonal Growth by SNAP-25 Antisense Oligonucleotides in
		vitro and in vivo; Nature; 29 July 1993; Vol. 364; 445-448.
	CX	Pearce, L. B., et al.; Pharmacologic Characterization of Botulinum Toxin for Basic Science
	l	and Medicine; Toxicon (1997); Vol. 35, No. 9; 1373-1412.
	CY	Ragona, et al.; Management of Parotid Sialocele with Botulinum Toxin; Laryngoscope,
		109:August 1999; p. 1344-36
	CZ	Ransom, B.R., et al.; Mouse Spinal Cord in Cell Culture. I. Morphology and Intrinsic
		Neuronal Electrophysiologic Properties; Journal of Neurophysiology; Vol. 40, No. 5; Sept.
		1977; 1132-1150.
	DA	Ransom, B.R., et al.; Mouse Spinal Cord in Cell Culture. II. Synaptic Activity and Circuit
,		Behavior; Journal of Neurophysiology; Vol. 40, No. 5; Sept. 1977; 1151-1162.
_	DB	Ransom, B.R., et al.; Mouse Spinal Cord in Cell Culture. III. Neuronal Chemosensitivity and
		its Relationship to Synaptic Activity; Journal of Neurophysiology; Vol. 40, No. 5; Sept. 1977;
		1163-1177.
	DC	Rees, H., et al.; Do Dorsal Root Reflexes Augment Peripheral Inflammation?; Neuro Report;
·		Vol. 5, No. 7; 21 March 1994; 821-824.
	DD	Sanchez-Prieto, J., et al.; Botulinum Toxin A Blocks Glutamate Exocytosis from Guinea-Pig
	ĺ	Cerebral Cortical Synaptosomes; Eur. J. Biochem. (1987); 165:675-681.

EXA	٩M	${ m I\! I\! N}$	IER

DATE CONSIDERED

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FORM PTO-1449

LIST OF ART CITED BY APPLICANT

ATTY. DOCKET:	17328(AP)	SERIAL NO.:
APPLICANT:	AOKI et al.	TITLE: METHOD FOR TREATING PAIN BY PERI- PHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE:	(Herewith)	GROUP:

OTHER ART (Continued)

(Including Author, Title, Date, Pertinent Pages, etc.)

DE	Shantz, E.J., et al.; Properties and Use of Botulinum Toxin and Other Microbial Neurotoxins in Medicine; Microbiol Rev.; 56:80-99 (1999).
 - DE	
DF	Simpson, L.; Botulinum Toxin: Potent Poison, Potent Medicine; Hospital Practice; April 15,
	1999; 34(4):87-91.
DG	Singh, B.R.; Critical Aspects of Bacterial Protein Toxins; Natural Toxins II (1996); Plenum
 1	Press, New York; pp. 63-84.
DH	Tonra, J. R., et al.; Axotomy Upregulates the Anterograde Transport and Expression of
1	Brain-Derived Neurotrophic Factor by Sensory Neurons; The Journal of Neuroscience; June
	1, 1998; 18(11):4374-4383.
DI	Tsuda, M., et al.; In vivo Pathway of Thermal Hyperalgesia by Intrathecal Administration of
	α, β -methylene ATP in Mouse Spinal Cord: Involvement of the Glutamate-NMDA Receptor
 	System; Br. J. Pharmacol (1999); 127(2):449-456.
DJ	Wiegand, H., et al.; The Action of Botulinum A Neurotoxin on the Inhibition by Antidromic
ŀ	Stimulation of the Lumbar Monosynaptic Reflex; Naunyn-Schmiedeberg's Arch. Pharmacol.
	(1977); 298:235-238.
 DK	Wiegand, H., et al.; I-Labelled Botulinum A Neurotoxin: Pharmacokinetics in Cats After
	Intramuscular Injection; Nauyn-Schmiedeberg's Arch. Pharmacol.; 292, 161-165 (1976).
DL	Williamson, L. C., et al.; Clostridial Neurotoxins and Substrate Proteolysis in Intact
	Neurons; The Journal of Biological Chemistry; Mar. 29, 1996; Vol. 271:13; 7694-7699.
DM	Williamson, L. C., et al.; Differential Effects of Tetanus Toxin on Inhibitory and Excitatory
	Neurotransmitter Release from Mammalian Spinal Cord Cells in Culture; Journal of
	Neurochemistry; 1992; Vol. 59:6; 2148-2157.
DN	Willis, W. D.; Pain; The Rat Nervous System; Second Edition; 1995; Academic Press, Inc.;
	pages 725-750.
DO	Woolf, C. J., et al.; Neuropathic Pain: Aetiology, Symptoms, Mechanisms, and Management;
	The Lancet; June 5, 1999; Vol. 353; 1959-1964.
DP	Yaksh, T. L., et al.; Chronic Catheterization of the Spinal Subarachnoid Space; Physiology &
	Behavior (1976); Vol. 17:1031-1036.
 DQ	Zhou et al., <i>Biochemistry</i> ; 34:15175-15181 (1995).
`	2100 00 41, 2000,000,000, y, 37.131/3-13101 (1773).

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DATE CONSIDERED

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Application/Control No. Applicant(s)/Patent Under Reexamination 09/550,371 AOKI ET AL. Notice of References Cited Examiner Art Unit Page 1 of 1 Chih-Min Kam 1653

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	Α	US-6,261,572	07-2001	Donovan	424/239.1
	В	US-			
	С	US-			
	D	US-			
	Е	US-			
	F	US-			
	G	US-			
	Н	US-			
٦	ı	US-			
	J	US-			
	K	US-			
	L	US-			
7	М	US-			

FOREIGN PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
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NON-PATENT DOCUMENTS

$\overline{}$		NON-APENT DOCUMENTS
*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	w	
	x	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

	Notic of R ferences Cited				Application/Control No. 09/550,371 Examiner		Applicant(s)Petent Under Rooxeminetion AOKI ET AL		
							Art Unit		
					Ohih Min Kam		4084	Page 1	of 1
					Chih-Min Kam ENT DOCUMENTS		1663		
*		DOCUMENT NO.	DATE		NAME CLAS		SUBCLASS	PORCE	
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0	L.							0	0
	M							0	0
FOREIGN PATENT DOCUMENTS									
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interior i		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS	SOURCE APS	OTHER
	N	DOCUMENT NO. WO 95/17904	DATE Jul. 1995				SUBCLASS 38/16	SOURCE	
	20			COUNTRY	NAME	CLASS		APS	OTHER
0	(CORPLIANO)	WO 06/17904	Jul. 1995	COUNTRY	NAME Aoki et al.	CLASS A61K	38/16	SOURCE APS	OTHER
00	0	WO 06/17904	Jul. 1995	COUNTRY	NAME Aoki et al.	CLASS A61K	38/16	APS	OTHER
000	0 0	WO 06/17904	Jul. 1995	COUNTRY	NAME Aoki et al.	CLASS A61K	38/16	SOURCE APS	OTHER
0000	0 0	WO 06/17904	Jul. 1995	COUNTRY	NAME Aoki et al.	CLASS A61K	38/16	SOURCE APS	OTHER
00000	O P O R	WO 06/17904	Jul. 1995	US	NAME Aoki et al. Borodic et al.	CLASS A61K	38/16	SOURCE APS	OTHER
000000	O P O R S	WO 06/17904	Jul. 1995	US	NAME Aoki et al. Borodic et al.	CLASS A61K	38/16	SOURCE APS	OTHER
0000000	O P O R S	WO 96/17904 WO 94/18629	Jul. 1995 Jul. 1994	US US NON-PAT	NAME Aoki et al. Borodic et al.	A61K A61K	38/16	SOURCE APS DOCUME SOURCE	OTHER
000000	O P O R S	WO 96/17904 WO 94/18629	Jul. 1995 Jul. 1994	US US NON-PAT	NAME Aoki et al. Borodic et al. ENT DOCUMENTS	A61K A61K	38/16	SOURCE APS	OTHER SI OTHER NT
	P Q R S T	WO 96/17904 WO 94/18629	Jul. 1995 Jul. 1994	US US NON-PAT	NAME Aoki et al. Borodic et al. ENT DOCUMENTS	A61K A61K	38/16	BOURCE APS DOCUME SOURCE APS	OTHER OTHER OTHER
	O P Q R S T	WO 96/17904 WO 94/18629	Jul. 1995 Jul. 1994	US US NON-PAT	NAME Aoki et al. Borodic et al. ENT DOCUMENTS	A61K A61K	38/16	BOURCE APS DOCUME SOURCE APS	OTHER OTHER OTHER

^{*}A copy of this reference is not being furnished with this Office action. (See Manual of Patent Examining Procedure, Section 707.05(a).)
**APS encompasses any electronic search i.e. text, image, and Commercial Databases.
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Notice of References Cited